

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 2 CASES</b>	

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION  
TO EXCLUDE THE OPINIONS AND TESTIMONY OF SHELBY THAMES, PH.D.**

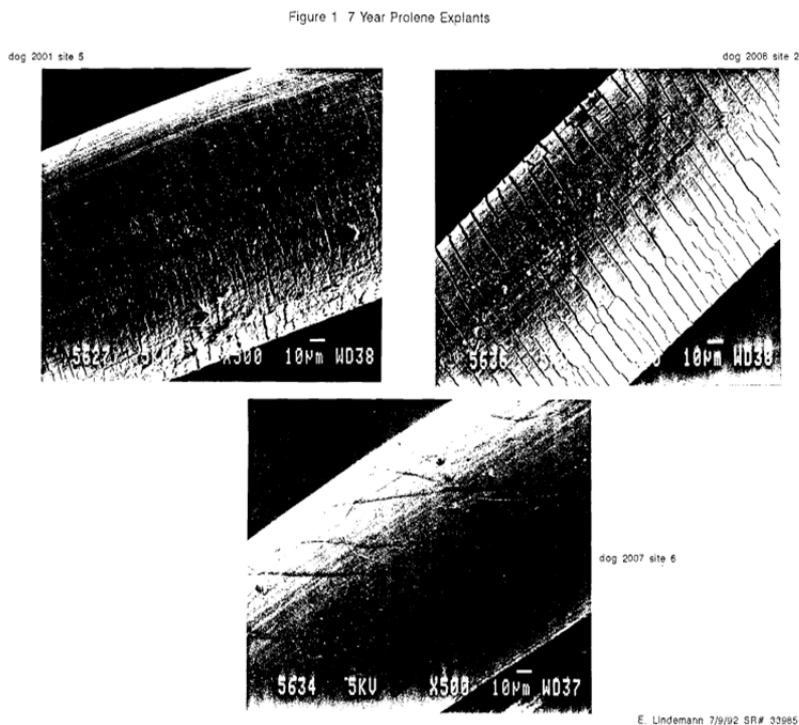
Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response to Plaintiffs' Motion [ECF 2455 ("Mot.")] and Memorandum of Law in Support of Plaintiffs' Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. [ECF 2458 ("Mem.")] (collectively, the "Motion"). The cases to which this Response applies are identified in Ex. A.

**INTRODUCTION**

Dr. Shelby Thames is an internationally-recognized polymer chemist who founded the Department of Polymer Science at the University of Southern Mississippi in 1969. Plaintiffs' motion does not challenge his qualifications as a polymer scientist. In fact, he and Dr. Kevin Ong have recently been recognized by the International Urogynecological Association for their paper, *The Myth: In Vivo Degradation of Polypropylene-based Meshes*, which has been accepted for publication in the International Urogynecology Journal. The IUGA has honored their work with its Best Basic Science Award, and he has been asked to speak at their 2016 annual meeting in September.

**Dr. Thames's opinion: Plaintiffs have not shown that Prolene undergoes meaningful degradation *in vivo* because there is no scientifically valid data to support the claim that Prolene oxidizes or degrades in the human body**

From the 1980s up to 1992, Ethicon conducted internal tests to determine what happens to Prolene polypropylene suture after it is implanted in the human body. *See* Motion Exs. T-Y. Although no degradation could be observed with the naked eye, an examination using a scanning electron microscope (SEM) showed surface cracking in some of the explanted sutures.<sup>1</sup> That led to the conclusion in some of the documents that the surface was degrading even though antioxidants had been added to prevent that. *See* Motion Ex. Y. A “7-Year Dog Study” found that surface cracking was greater on Prolene filaments than on filaments of another substance PVDF.<sup>2</sup> One of the Prolene filament photographs from the dog study looked like this:



<sup>1</sup> “Degradation” is not a defined term, and is commonly used to refer to numerous distinct phenomena, including surface cracking, the loss of physical properties, and the loss of molecular weight.

<sup>2</sup> Significantly, no Ethicon tests state or infer that Prolene implanted in the human body is subject to clinically significant degradation, with the sole exception of ocular sutures exposed to UV radiation.

The company scientists conducting the dog study concluded that this surface cracking showed “degradation,” but that it had no clinical significance, *i.e.*, did not cause any harm to the patients in whom the sutures were implanted. Ex. B, Weisberg 11/13/15 Dep. 450:23-451:9.

This litigation began in 2012. There is still no reliable scientific study that shows that Prolene degrades *in vivo* in the pelvic floor in any clinically significant way. And Plaintiffs have offered no expert witness who has identified the extent to which Prolene degrades by reliable analytical techniques, or offered any explanation other than *ipse dixit* as to how this alleged degradation caused injury to these plaintiffs.<sup>3</sup> Nevertheless, after looking at company documents, Plaintiffs’ counsel deposed Ethicon on the issue in January of 2014. When examined, Ethicon’s witness, Dr. Thomas Barbolt, admitted that certain tests identified surface degradation in Prolene sutures, but asserted his opinion as the Ethicon company witness that the degradation was not “significant” because the testing showed no reduction in the molecular weight or tensile strength of the explanted Prolene sutures. For instance:

Q. Are you telling the ladies and gentlemen of the jury that when the outer surface of the polypropylene fibers crack and peel away from the surface, that that is not degradation?

...

[A.] I am telling listeners that the key endpoint of adverse effects of degradation are molecular weight and tensile strength, both quantitative measures, not subjective assessments of surface changes, but quantitative measures that hold great weight and suggest that there’s no degradation to the Prolene fiber in terms that are significant.

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<sup>3</sup> Dr. Vladimir Iakovlev’s opinions that he observes degradation on Prolene that causes clinical complications is unreliable because (i) the theory underlying his degradation opinion has been disproven, and (ii) his opinions regarding complications are pure *ipse dixit* at odds with known scientific and medical facts. See Notice of Adoption of Prior *Daubert* Motion of Dr. Vladimir Iakovlev, M.D. for Wave 2; see also Mem. Supp. Mot. to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev, *In re Ethicon, Inc.*, MDL 2327, No. 2:12-cv-01267 [ECF 2070].

Ex. C, Barbolt 1/8/14 Dep. 373:24–375:6; *see also id.* at 448:19–449:16 (explaining the study reported “no evidence of degradation that’s meaningful.”).

Ethicon has made repeated *Daubert* objections to the admission of any testimony about degradation when there is no scientific test or study that has ever shown that degradation of Prolene in the pelvic floor, if any, is clinically significant. *See Ethicon Inc. v. Batiste*, 2015 Tex. App. LEXIS 11517 at \*27 (Tex. App. Nov. 5, 2015), *pet. pending* (no evidence as to the amount of degradation necessary to have clinical effect). To date, those objections have been overruled.

In addition, Ethicon has hired Dr. Thames to examine the question. He has now studied 50 samples of Prolene mesh explanted from the pelvic floor, and it is his opinion that the explanted filament pictured above was not completely cleaned. His analysis confirms that the cracked surface is protein from the body, and not degraded Prolene. With the help of Dr. Kevin Ong, he has used a more thorough cleaning process not used by Ethicon in any of the testing cited by plaintiffs and shown that it removes the protein. And he deliberately degraded a clean Prolene fiber and shown that, when it cracks, it does not look like the photograph above.

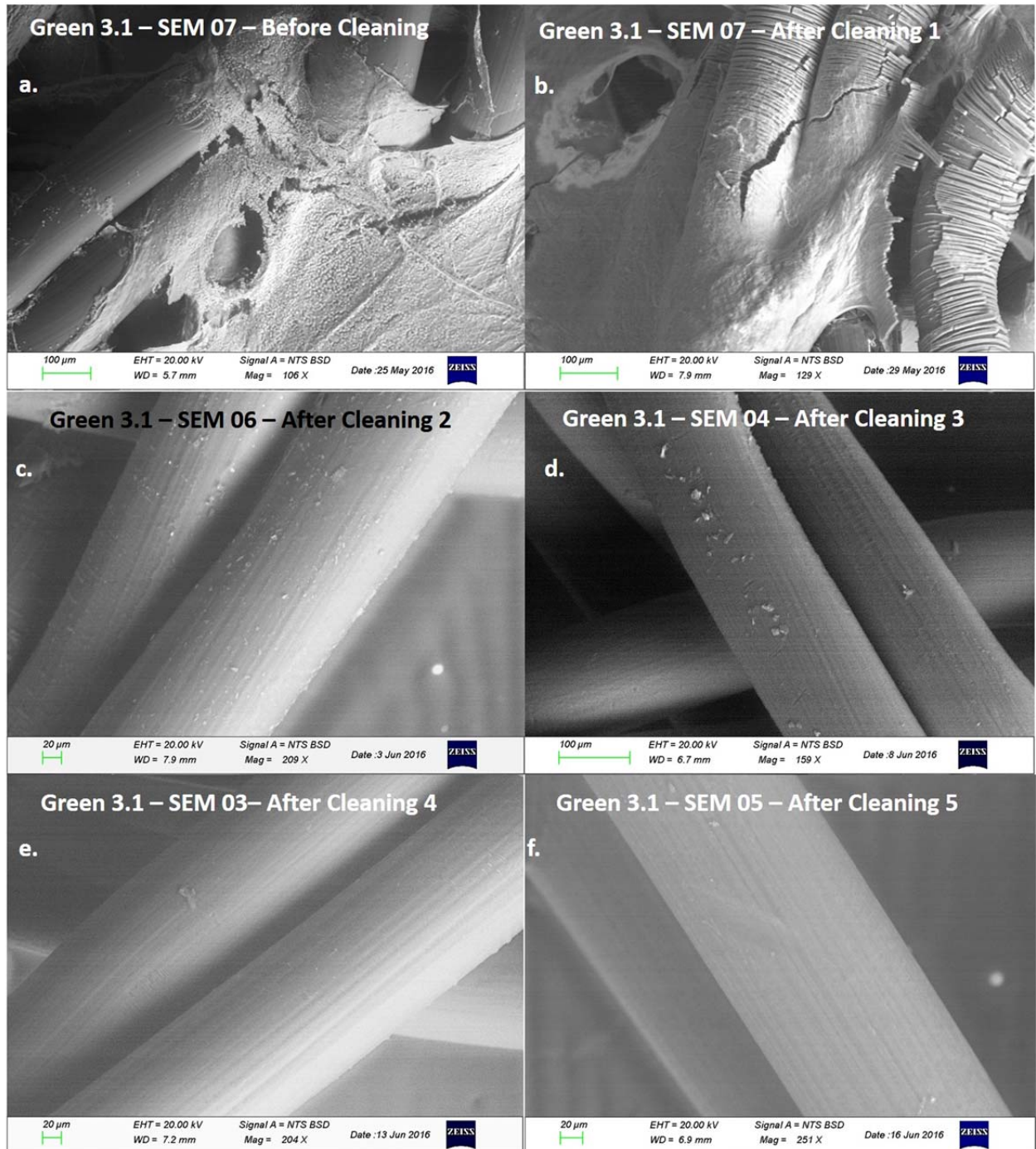
For each of the following reasons, his opinion is that Plaintiffs have not shown that Prolene undergoes meaningful degradation in the pelvic floor, and, in fact, there is no valid scientific data to show that it oxidizes or degrades in the pelvic floor.

**No loss of molecular weight.** Ethicon’s dog study did not show a significant loss of molecular weight and if there had been oxidation, that weight would have gone down. Mot. Ex. D, Thames Report at 6, 8-10, 27-29.

**No loss of toughness.** While the dog study data show a slight loss of tensile strength, it was accompanied by a significant increase in elongation, the result of which is the “toughness” of the fiber. If there had been oxidation, the tensile strength would have declined significantly

and toughness would have decreased. *Id.* at 7-11, 27-28.

**The effect of cleaning.** Dr. Thames's cleaning process goes in stages. Stage 1 cleaning looks like the photograph above, but the subsequent photos do not. The sequence<sup>4</sup> is as follows:

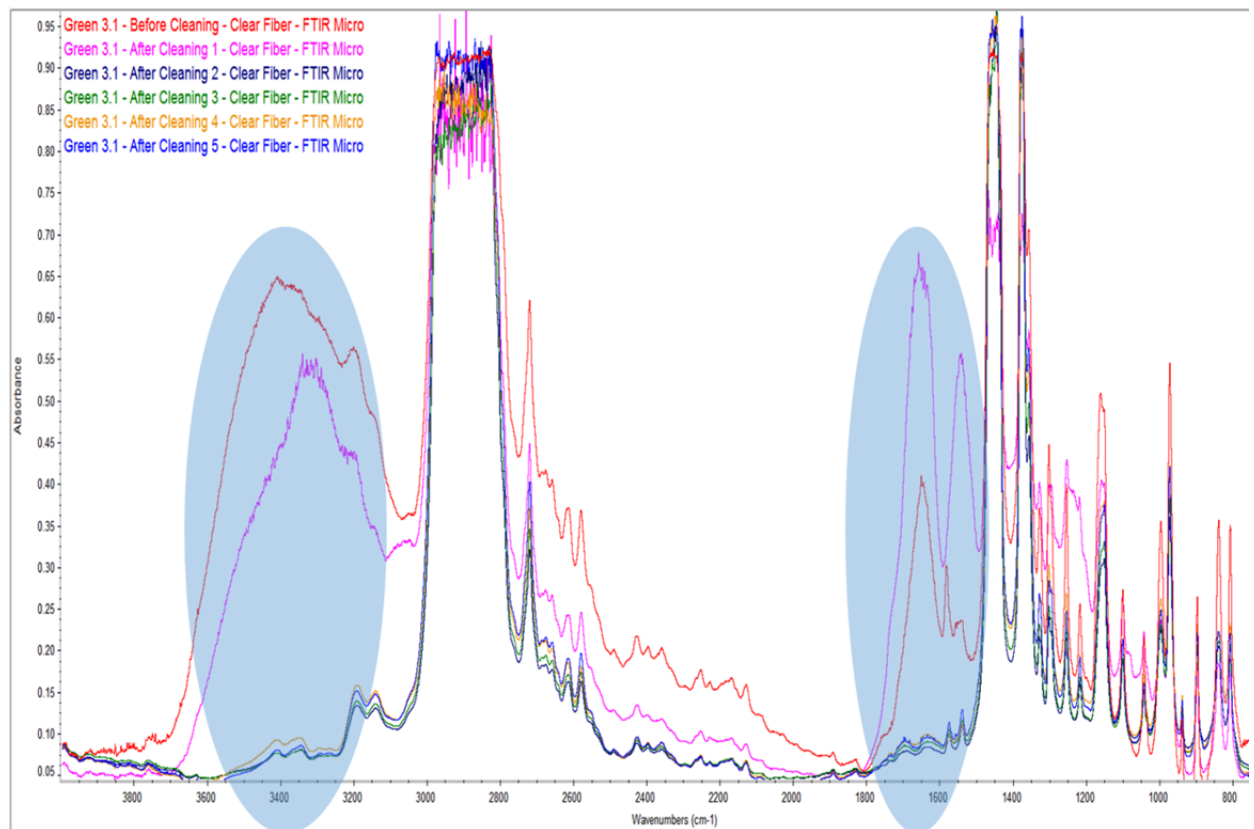


<sup>4</sup> Ex. D, Case Specific Report of Shelby F. Thames, Ph.D., *Green v. Ethicon, Inc.*, at 22 (June 17, 2016).



**Extrusion lines.** When the mesh is cleaned, lines in the filament left when the polypropylene is extruded become visible. They are not generally visible before cleaning.

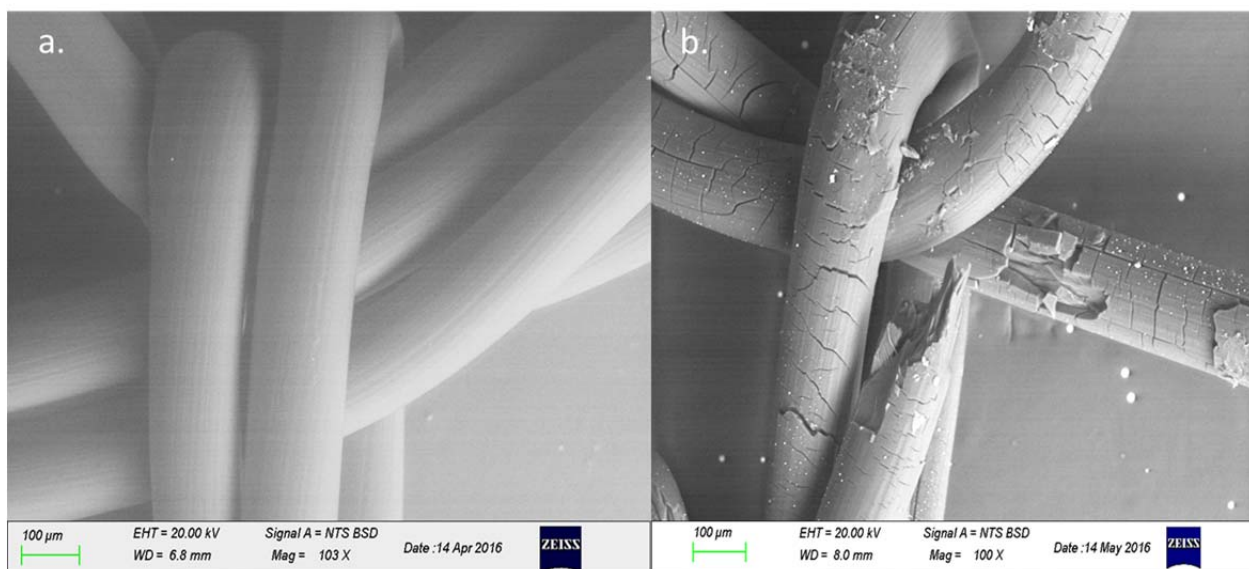
**FTIR analysis.** To demonstrate that what the cleaning removes is protein, and not oxidation, he has done a sequential Fourier Transform Infrared Spectroscopy (“FTIR”) analysis in which the spectrum changes show that it is protein that is being removed.<sup>5</sup> The blue shading shows the protein peaks on the spectrum. Plaintiffs have made no effort to replicate this testing.



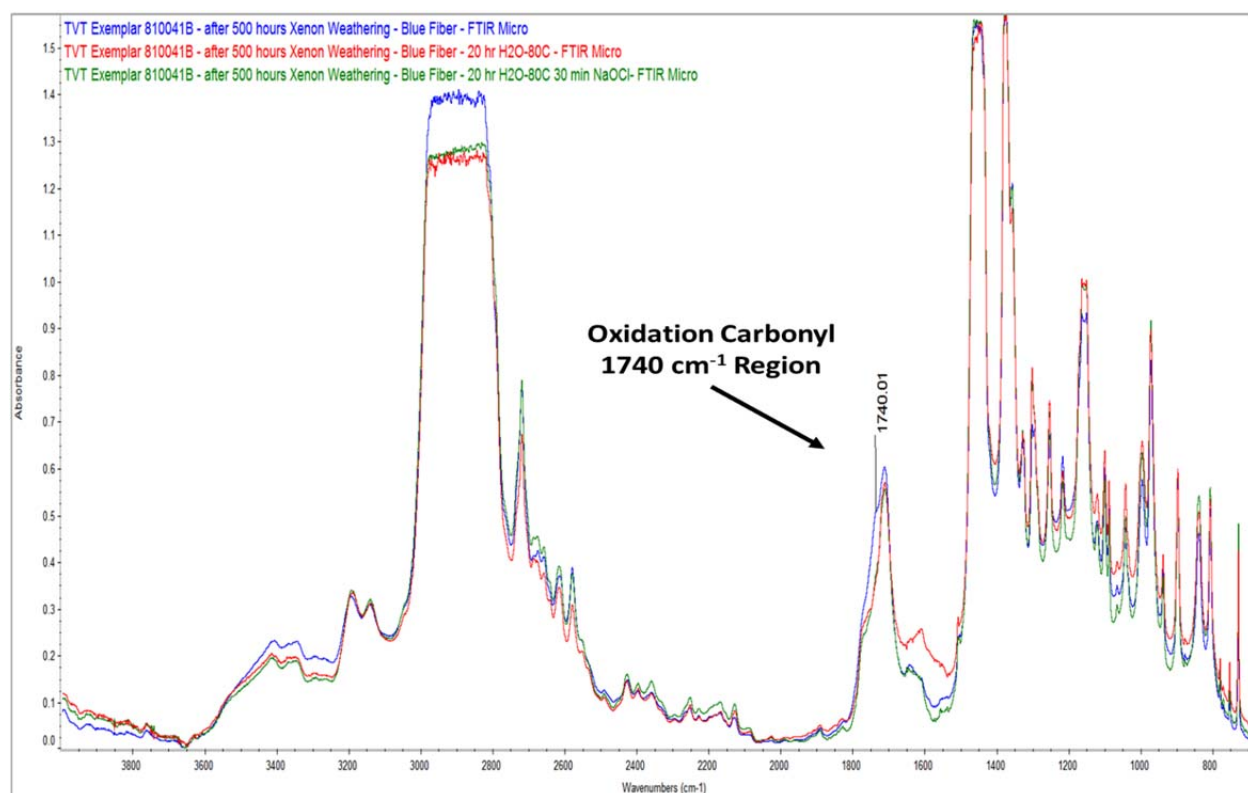
**Oxidized sample.** It is well known that ultraviolet light will oxidize polypropylene. Dr. Thames has now exposed a pristine filament of Prolene to ultraviolet light long enough to cause oxidation. The remaining cracks<sup>6</sup> are deep, irregular, and random:

<sup>5</sup> Ex. D, Case Specific Report of Shelby F. Thames, Ph.D., *Green v. Ethicon, Inc.*, at 14 (June 17, 2016).

<sup>6</sup> Ex. E, Intentional Oxidation of Prolene Mesh, Supplemental Report of Dr. Shelby F. Thames (“Supplemental Report”) (submitted Aug. 8, 2016).



The 1740 peak in the FTIR<sup>7</sup> after Cleaning 4 shows cleaning did not remove the oxidation:



<sup>7</sup> Ex. E, Supplemental Report.

**PVDF.** Dr. Thames’s opinion is that the reason why the Prolene in the “7-Year Dog Study” showed surface cracking described by the scientists as degradation while PVDF did not is that Prolene is a polymer to which protein adheres while PVDF is more like Teflon and protein does not stick to it as readily. Ex. F, *Batiste* Trial Tr. 99:13-101:18.

Plaintiffs have no scientific answer to this evidence. They have notably not tried to replicate or challenge the opinions of Dr. Thames by their own reliable scientific testing. Their expert, Dr. Howard Jordi, admitted that he also could not find a significant change in molecular weight in the explants he examined. Ex. G, Expert Report of Dr. Howard Jordi, at 84 (May 20, 2014). None of Plaintiffs’ experts conducted FTIR analysis on properly cleaned mesh explants.

With two exceptions, they have not examined deliberately oxidized polypropylene. First, although Dr. Scott Guelcher sought to use a chemical solution to prove that Prolene oxidizes, this Court found Dr. Guelcher’s testing to be unreliable, and he no longer relies on it in this litigation. *See* Mem. in Supp. of Mot. to Exclude Scott A. Guelcher, Ph.D., at 4-8 [Dkt. #1981]. Second, Dr. Jimmy Mays reported that heated polypropylene “started to degrade around 230-250 degrees Celsius,” but the Court excluded the evidence because normal body temperature is only about 37° C. *Mathison v. Boston Sci. Corp.*, 2015 WL 2124991, at \*12 (S.D. W. Va. May 6, 2015).

Because they have no scientific answer and no reliable scientific testing, Plaintiffs have moved to exclude Dr. Thames’s testimony. There is no basis for any of their objections.

**I. Rule 30(b)(6) does not prevent Dr. Thames from opining that Plaintiffs have not proved that Prolene undergoes meaningful degradation *in vivo* because there is no valid scientific data to show that Prolene oxidizes or degrades in the human body.**

Plaintiffs’ argument that Dr. Thames’s degradation opinions are barred due to the testimony of Dr. Thomas Barbolt—Ethicon’s Rule 30(b)(6) representative—is predicated on an incomplete and misleading representation of Dr. Barbolt’s testimony regarding the alleged degradation of Prolene. *See* Motion at 2-3, 5-8. A full reading of Dr. Barbolt’s testimony shows



that he referred to subjective observations of surface cracking, not the objective assessments necessary to establish whether Prolene meaningfully degraded *in vivo*. For instance:

Q. Are you telling the ladies and gentlemen of the jury that when the outer surface of the polypropylene fibers crack and peel away from the surface, that that is not degradation?

...

[A.] I am telling listeners that the key endpoint of adverse effects of degradation are molecular weight and tensile strength, both quantitative measures, not subjective assessments of surface changes, but quantitative measures that hold great weight and suggest that there's no degradation to the Prolene fiber in terms that are significant.

Ex. C, Barbolt 1/8/14 Dep. 373:24–375:6; *see also id.* at 448:19–449:16 (explaining the study reported “no evidence of degradation that’s meaningful.”).

In other words, Dr. Barbolt testified that certain Ethicon tests contain subjective observations that some Prolene fibers exhibited surface cracking, but there had been no quantitative testing to determine whether the Prolene meaningfully degraded. Thus, Dr. Barbolt’s testimony is consistent with Ethicon’s position in this litigation, as well as Dr. Thames’s opinion that “Ethicon’s Prolene material does not undergo meaningful or harmful degradation *in vivo*.” Mot. Ex. D, Thames Report at 13. Although Dr. Thames goes one step further by definitively showing the cracked material is protein, his opinion remains consistent with Dr. Barbolt’s testimony.

For this reason, the Court need not consider *Rainey v. American Forest & Paper Ass’n, Inc.*, 26 F. Supp. 2d 82, 94 (D.D.C. 1998). But it would not control here in any case.

To begin with, *Rainey* does not prohibit the offering of testimony that was “not known or inaccessible” at the time of the Rule 30(b)(6) deposition. *Id.* at 94. Before this litigation, Ethicon had no reason to explore the alleged degradation of Prolene further because there was no

evidence that it had any clinical significance. It was only when the issue became legally significant that Dr. Thames was hired to examine issues regarding degradation, which he has done over an extended period of time.

Moreover, *Rainey*'s reading of Rule 30(b)(6) is just wrong. Rule 30(b)(6) testimony is not "binding" in the same sense as a judicial admission. *See, e.g., A.I. Credit Corp. v. Legion Ins. Co.*, 265 F.3d 630, 637 (7th Cir. 2001) ("Nothing in the advisory committee notes indicates that [Rule 30(b)(6)] goes so far" as to be "absolutely binding" on a corporation); 8A Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice and Procedure* § 2103 (3d ed.) (explaining that Rule 30(b)(6) deposition testimony is "not 'binding' in the sense that the corporate party is forbidden to call the same or another witness to offer different testimony." ).<sup>8</sup>

For all of these reasons, there is nothing in Rule 30(b)(6) or Dr. Barbolt's testimony that prohibits Dr. Thames from testifying in this litigation.

## **II. Dr. Thames's individual opinions are grounded in both evidence and science**

Plaintiffs' rambling diatribe fails to explain Dr. Thames's opinions and substitutes conclusory invective for relevant analysis. The answers are as follows:

### **A. Dr. Thames has a scientific basis for concluding that protein, not oxidation, produced the FTIR peak in the 7-Year Dog Study.**

In the "7-Year Dog Study," Ethicon scientist Daniel Burkley thought it was significant that "a broadened weak absorbance at about 1650 cm" was "possible evidence of slight

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<sup>8</sup> *See also Keepers, Inc. v. City of Milford*, 807 F.3d 24, 34-35 (2d Cir. 2015), *petition for cert. filed*, No. 15-1487 (June 9, 2016) ("Nothing in the text of the Rule or the Advisory Committee notes indicates that the Rule is meant to bind a corporate party irrevocably to whatever its designee happens to recollect during her testimony."); *R&B Appliance Parts, Inc. v. Amana Co., L.P.*, 258 F.3d 783, 786 (8th Cir. 2001) ("Although [a company] is certainly bound by [it's Rule 30(b)(6) designee's] testimony, it is no more bound than any witness is by his or her prior deposition testimony."); *United States v. Taylor*, 166 F.R.D. 356, 362 n.6 (M.D.N.C. 1996) ("When the Court indicates that the Rule 30(b)(6) designee gives a statement or opinion binding on the corporation, this does not mean that said statement is tantamount to a judicial admission." ).

oxidation.” Mot. Ex. D, Thames Report at 6 (stating that Burkley “mis-assign[ed]” the FTIR frequency).

In disagreeing with Mr. Burkley’s statement, Dr. Thames relies on scientific literature that establishes the absorption frequencies for oxidized polypropylene and proteins. The dog study contains no indication that the fibers were cleaned of proteins before the examination. Mot. Ex. D, Thames Report at 6; *see also* Ex. H, ETH.MESH.09888189 (reporting that “[m]ost of the[] specimens were still surrounded with some tissue[.]”).

As shown above, when there are proteins on the fibers, the FTIR pattern resembles the one that Burkley observed, but the peaks are due to protein, not oxidation. It is only when the proteins are cleaned off that the oxidation peak in the correct 1740 range is observed. *Id.*; *see* Mot. Ex. D, Thames Report at 23-25 (explaining that scientific literature has established different absorption frequencies for oxidized polypropylene and proteins). This FTIR analysis is accepted science.

**B. Plaintiffs’ expert agrees that the molecular weight changes were not significant.**

The dog study reported the following molecular weight data after the fibers at issue had been implanted for seven years. The “control” specimen was not implanted and its weight, along with the ones that were implanted, are shown as follows:

<b>Specimen</b>	<b>Mw</b>	<b>Mn</b>
Prolene 4/0 (control)	324,000	60,000
Site 1 Dog #2007	322,000	69,000
Site 6 Dog #2007	323,000	63,000
Site 3 Dog #1995	327,000	59,000

Site 3 Dog #2019	331,000	64,000
Site 2 Dog #2019	332,000	57,000
Site 2 Dog #2008	322,000	53,000

*See* Ex. H, ETH.MESH.09888218-22 (reporting molecular weight determinations made in 1992 using GPC). Dr. Thames did not in any way “manipulate” these numbers. He just expressed an opinion about them.

In Dr. Thames’s opinion, these data show that the molecular weight changes in the sutures were not “significant” or “meaningful.” Mot. Ex. D, Thames Report at 6, 8-10, 27-29. Based on the absence of a meaningful loss of molecular weight, Dr. Thames concludes that there has been no meaningful degradation of the Prolene fibers at issue. *See id.* at 6, 8, 29.

Dr. Thames’s opinion is confirmed by the opinion and work of Plaintiffs’ expert—Dr. Howard Jordi—who previously performed similar molecular weight testing on 15 explant samples and several control Prolene samples, and confirmed the findings of the dog study. *See* Ex. G, Expert Report of Dr. Howard Jordi, at 84 (May 20, 2014). Specifically, Dr. Jordi reported that “[t]he control and explant samples *do not show a significant difference* in molecular weight.” *Id.* (emphasis added). Indeed, he conceded that the “Jordi GPC analysis of both control and explant samples tends to confirm ‘The 7 Year Dog Study’ performed at Ethicon . . . in that little to no macro MW degradation was noted.” *Id.* at 10.

Plaintiffs now object to Dr. Thames’s agreement with Mr. Burkley and Dr. Jordi that the drop is not “significant” but they offer no opinion as to what kind of change would be “significant” and offer no literature to rebut this opinion.

**C. Dr. Thames has a scientific basis for finding that the dog study showed “toughness” increased and that demonstrates no degradation.**

As Dr. Thames reports, polymer chemists routinely assess the “toughness” of a material by analyzing the relationship between the force required to *break* the material—known as tensile strength or stress—and the extent a material *lengthens* before it ruptures—known as elongation or strain. Mot. Ex. D, Thames Report at 7. When these data points are plotted along the x- and y-axes of a graph, the area under the resulting line defines the material’s toughness. *Id.*

Applying this foundational concept of polymer science to the data from the dog study, Dr. Thames found that Prolene’s toughness improved after implantation. Specifically, Dr. Thames analyzed data collected in the dog study at years 0, 1, 2, and 7, where each data point represented an average of five determinations as required by ASTM protocols. *See* Ex. I, Data Summary of Ten Year Prolene BSR Study, ETH.MESH.11336182-83 (“BSR Data Summary”). Dr. Thames then plotted this data to create a stress-strain curve for the seven-year duration of the study, and incorporated this curve in his Report. Mot. Ex. D, Thames Report at 8. Based on this work, Dr. Thames concluded that the area under the stress-strain curve increased over time, meaning that toughness increased over time. *Id.* at 7-8.

Grasping at straws, Plaintiffs argue that the dog study did not record the data necessary to compute toughness values. Motion at 12. Importantly, Plaintiffs offer no testing or relevant scientific support for their claim that Dr. Thames’s opinions are not reliable. Plaintiffs’ assertion is simply wrong, and underscores Plaintiffs’ flawed conception of basic polymer science.

The dog study reports stress-strain data including modulus, breaking strength (or, “stress”), and elongation (or, “strain”), which were generated during tensile testing of pristine and explanted sutures. *See* Ex. I, BSR Data Summary. Modulus is a *series* of stress-strain data that begins at the origin (*i.e.*, point 0,0 on a graph), and defines the elastic (*i.e.*, linear) behavior



of the tested material. *See* Ex. J, J. Gere & S. Timoshenko, *Mechanics of Materials*, 14 (1997) (defining modulus as the “slope of the straight line” between the origin and the point where stress and strain cease to have a proportional relationship). The breaking strength and the elongation at the breaking point define the ending point of the same stress-strain relationship. *See id.* at 14-15 (explaining the correlation between breaking strength and elongation).

By analyzing the origin point, the recorded modulus, the recorded breaking strength, and the recorded elongation, and applying fundamental principles of polymer science, Dr. Thames constructed a representative stress-strain curve for the fibers tested in the dog study. *See* Mot. Ex. D, Thames Report at 7-8; *see also* Ex. J, Gere, at 14-15 (explaining the relationship among the components of a stress-strain curve); Ex. K, F. Miller & H. Doeringsfeld, *Mechanics of Materials*, at 22-24 (same). He then used these stress-strain curves to compare the toughness of the fibers, and found that the fibers that had been implanted for seven years became tougher. *See* Mot. Ex. D, Thames Report at 8.

Dr. Thames’s approach is not simply conjecture, as it has been practiced in the polymer industry for decades. Indeed, scientists and engineers routinely deduce toughness from modulus, breaking strength, and elongation data reported in this manner on technical data sheets for commercially available polymers. *See, e.g.*, Ex. L, Prospector INEOS PP H00G-00 Technical Data Sheet (listing values for tensile strength, tensile elongation, and modulus); Ex. M, Sabic PP PCGH10 Technical Data Sheet.

Plaintiffs’ expert, Dr. Scott Guelcher, claimed that he could not assess toughness from Dr. Thames’s stress-strain curve. Motion at 13 n.40. But Dr. Guelcher also failed ground his assertion in scientific support or in any testing to challenge the opinions. In other words, Plaintiffs’ objection is based solely on their expert’s *ipse dixit*.

**D. Dr. Thames used reliable scientific methods to determine that the “flakes” of material removed from the Prolene by cleaning were protein, and the “extrusion lines” that remain are visible.**

In order to determine the composition of the material on the filaments shown on page 5, *supra*, Dr. Thames analyzed the mesh fibers using techniques generally accepted in the field of polymer chemistry: light microscopy, SEM to produce the image of the fibers, and FTIR to analyze the contents. *See* Mot. Ex. D, Thames Report at 5-12 (discussing testing process). On the basis of this testing, Dr. Thames found that the “Prolene fiber” in the photographs “is encased within a dry and cracked proteinaceous layer[.]” *Id.* at 104 (noting that the protein “structures was confirmed by FTIR microscopy.”).

Specifically, Dr. Thames tested Prolene fibers from a pristine exemplar and a mesh explant before, during, and after subjecting the fibers to a cleaning process designed to remove protein from the surface. *See id.* at 5-8. Dr. Thames analyzed the fibers using light microscopy, SEM, and FTIR at each stage of the cleaning process. *See id.* at 5-12. As the cleaning process progressed, the translucent coating and flakes adhered to the surface of the fibers diminished and ultimately disappeared. *See supra* at 5; *see also* Mot. Ex. D, Thames Report at 7, 10-12.

The FTIR data of the uncleaned explant fibers show strong carbonyl peaks in the area of the spectrum consistent with proteins, *i.e.* the blue shaded areas on page 6 above. Conversely, the FTIR data on explant fibers after cleaning demonstrate that the protein carbonyl peaks disappeared from the FTIR spectrum. *See supra* at 6; *see also* Mot. Ex. D, Thames Report at 8 (showing disappearance of carbonyl peaks associated with proteins as cleaning progresses).

With respect to extrusion lines, they are visible on some scanning electron microscope photographs and not on others. His observations about them are nothing more than what is obvious in the photographs.

Dr. Thames used reliable scientific methods. Not only are his methods supported by the literature, but his results will soon be published in a peer-reviewed journal. This is exactly what an expert is supposed to do to satisfy the demands of *Daubert*.

**E. Dr. Thames's cleaning protocol is based on scientific methods and its accuracy is confirmed by the FTIR analysis.**

Dr. Thames's progressive FTIR analysis shows that his cleaning process removed protein from the sample, not oxidized Prolene. It showed that there was no oxidized Prolene in the first place. Plaintiffs ask the impossible when they say "Dr. Thames did not determine what effect, if any, the various steps of his cleaning protocol had on oxidized Prolene. Motion at 17. It is impossible to show "effects" on something that is not there.

As Dr. Thames explains in his Report, proper scientific methodology requires the removal of biological materials, including proteins, from a mesh explant to permit a proper analysis of the mesh fiber itself. *See, e.g.*, Mot. Ex. D, Thames Report at 15-17. He notes mesh explants are covered with proteins upon excision, and are preserved in formalin, which contains formaldehyde. *Id.* at 11. Dr. Thames advises that a chemical reaction occurs when proteins are exposed to formaldehyde, which results in a "hard, brittle and insoluble" "polymeric shell" adhered to the mesh fibers. *Id.*; *see also id.* at 17. Thus, the crosslinked formaldehyde-protein shell must be removed before analysis of the mesh. *Id.* at 11. That is what Dr. Thames has done.

Because no ISO protocol exists for cleaning mesh explants, Dr. Thames used his knowledge of basic organic chemistry to develop a cleaning protocol. Over the course of 25 steps, he placed the formalin-fixed explant in distilled water heated to 70° C, then adds bleach and Proteinase K—an enzyme that denatures proteins. Mot. Ex. D, Thames Report at 102-03 (discussing cleaning protocol). Importantly, Dr. Thames's cleaning solution only removes water-

soluble substances—like proteins—while leaving the chemical structure of insoluble substances—like oxidized and non-oxidized Prolene—intact. *Id.* at 103-04.

In arguing that Dr. Thames improperly failed to use a control to assess his cleaning protocol, Plaintiffs appear to misapprehend the purpose of a control. *See* Motion at 18-20. As Dr. Thames explains, experimental controls are only necessary to control variables. Mot. Ex. D, Thames Report at 104-05. In the absence of a variable, proper scientific methodology does not require a control. In any event, as shown on page 7, *supra*, Dr. Thames has now cleaned intentionally-oxidized Prolene down to Cleaning 4 and has shown that it does not remove oxidation. The peak after Cleaning 4 on that FTIR has no counterpart in the Cleaning 4 FTIR for implanted mesh. *Compare supra* at 6 with *supra* at 7.

**1. The study on which Plaintiffs rely does not support their conclusion.**

Plaintiffs argue that Dr. Thames’s opinions are unreliable because he merely “assumed” that his cleaning protocol would not affect oxidized Prolene. Motion at 17. They claim that Dr. Thames’s “use of Proteinase K, sonication and shaking, water, heat and bleach” in his cleaning protocol “could have destroyed evidence of surface oxidation.” *Id.* Plaintiffs misinterpret the sole study to which they cite, and otherwise fail to identify scientific support for their position.

As an initial matter, Dr. Thames did not simply “assume[]” that his cleaning protocol would not affect oxidized Prolene. *See supra* at § VII.A; *infra* at § VII.D. Rather, Dr. Thames applied his specialized knowledge of chemistry to develop a cleaning methodology that would remove artifacts of the sample preparation process and permit proper analysis of the surface of the Prolene fiber. Importantly, Dr. Thames used generally accepted analytical tools—FTIR and SEM—throughout the cleaning process to monitor the effects of the cleaning protocol. Plaintiffs’

suggestion that Dr. Thames's application of specialized knowledge and generally accepted testing methods constitutes an "assum[ption]" is inconsistent with the teachings of *Daubert*.

Plaintiffs offer no scientific testing of their own to challenge the cleaning methodology used by Dr. Thames, when clearly that testing could have been done. The only scientific literature Plaintiffs identify to support their assertion that Dr. Thames's protocol "destroy[s] any evidence of oxidation" is the Mary study. Motion at 17 (quoting Mot. Ex. H). According to Plaintiffs, the Mary study proved that "stresses like shaking and sonication would remove the outer degraded layer from explanted Prolene." *Id.* But the Mary study's cleaning protocol did not use sonication or shaking. Mot. Ex. H, Mary, at 200-02. In fact, the Mary study incorporated a harsh cleaning protocol that bears no relationship to the methods used by Dr. Thames. *Compare id. with* Mot. Ex. D, Thames Report at 102-03.

Plaintiffs' arguments have no basis in science, and should be rejected by this Court.

**2. Because some FTIR lines evidence protein carbonyls and others evidence oxidation carbonyls, it is consistent with his opinion for Dr. Thames to testify that "carbonyls" are removed.**

FTIR is an analytical technique that permits scientists to determine the unique chemical composition of a material. Mot. Ex. D, Thames Report at 23. It produces spectra that show the chemical signature or fingerprint of surface material. *Id.* Specific chemicals in a material manifest in FTIR spectra as a specific band or "peak." *Id.* One such peak is associated with the presence of carbonyl groups, which are structural entities that possess carbon and oxygen atoms. *Id.* at 23-24.

Importantly, Dr. Thames explains that "FTIR spectra may include many different types of carbonyl bands[.]" Ex. N, Thames Aff. at ¶ 15. For this reason, the proper chemical identification of a material requires an understanding of the FTIR signatures for specific substances. Mot. Ex. D, Thames Report at 23 (reporting that "strong frequencies at 1539, 1653, and 3300 cm<sup>-1</sup> are



indicative of protein(s) and not PP and/or Prolene,” and “[c]arbonyl stretching” can “occur[] in the 1830 – 1650  $\text{cm}^{-1}$  region” on FTIR spectra).

On the other hand, if the Prolene in the explants had oxidized *in vivo*, oxidation carbonyl peaks with a unique FTIR fingerprint would have formed. Ex. N, Thames Aff. at ¶ 17; *see also supra* at 6-7; Mot. Ex. D, Thames Report at 23-24 (observing that scientific literature shows that oxidized polypropylene has a carbonyl peak at 1740  $\text{cm}^{-1}$ ).

Plaintiffs assume, contrary to science, that all carbonyls are the same and that all carbonyls indicate oxidation. They offer no support for this assumption, and its falsity torpedoes their argument. They argue that “[a]ccording to Dr. Thames, Proteinase K takes away carbonyls, but carbonyls are also what would be present on the mesh if it was oxidized.” Motion at 19. They point only to Dr. Thames’s deposition, where he testified that Proteinase K removes carbonyl peaks. Motion at 18 (quoting Thames Dep. Tr. 61:16-62:9).

But all carbonyls are not the same. The carbonyls that Proteinase K denatures are protein carbonyls. It has no effect on Prolene fibers, whether oxidized or not. Ex. N, Thames Aff. at ¶¶ 16-18. In other words, Proteinase K assists in the removal of protein carbonyl peaks, not oxidation carbonyl peaks. *Id.* at ¶ 15. For this reason, although Dr. Thames does not dispute that Proteinase K helps “take[s] away carbonyls,” Motion at 19, he explains that “Plaintiffs are using the term ‘carbonyls’ in a very generic sense that misrepresents the chemistry.” *Id.* at ¶ 15.

Fundamental principles of chemistry dictate that oxidized Prolene would be neither soluble in water nor affected by Proteinase K, so any oxidation carbonyl peaks would not have been destroyed by Dr. Thames’s cleaning process. Ex. N, Thames Aff. at ¶¶ 10, 17. Thus, if any oxidation carbonyl peaks had existed, the FTIR Dr. Thames conducted after each stage in the cleaning process would have included those peaks.

**F. Plaintiffs are mistaken in claiming that the literature they cite demonstrates the oxidation of Prolene in the human body**

The literature and tests Plaintiffs point to do not stand for the proposition that the Prolene in Ethicon mesh products degrades *in vivo*. See Motion at 1-2 nn.1-13. Many of the studies which Plaintiffs cite do not address Prolene, which contains antioxidants, and some even confirm the effectiveness of antioxidants. One Prolene study deals with ocular sutures, which are exposed to ultraviolet light. And another fails to take into account that antioxidants themselves can effect an FTIR reading. All of this is explained in Dr. Thames report, and none of it is rebutted in Plaintiffs Motion. See Mot. Ex. D, Thames Report at 12-19.

**CONCLUSION**

Plaintiffs' motion is fundamentally miscast. Dr. Thames has done what experts are supposed to do. He has performed standard tests, whose reliability is supported by the literature, to determine whether Prolene oxidizes and so degrades *in vivo*. Plaintiffs object that his testing has not been published, but their expert tests confirm that there is no significant loss of molecular weight and that heat does not degrade polypropylene until it reaches 230° C. Plaintiffs are free to see if they can reproduce Dr. Thames's tests, but they have not done that either. And now Dr. Thames's tests have been accepted for publication and even given a scientific award.

Plaintiffs bear the burden of showing that Prolene degrades in the pelvic floor, and that it does so to a degree that causes clinical complications. Dr. Thames has used accepted analytical techniques on the mesh at issue in this litigation to show that they have not degraded within the detection limits of those techniques. Plaintiffs have not shown otherwise. Absent any measurable degradation of Prolene, it cannot be said that any clinically significant degradation has occurred.

For these reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 2 CASES</b>	

**CERTIFICATE OF SERVICE**

I hereby certify that on August 8, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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